



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,743	07/03/2001	Krassen Dimitrov	P-IS 4548	3666

23601 7590 01/15/2003
CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

[REDACTED]
EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,743	DIMITROV, KRASSEN	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 December 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 16-77 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 and 78-84 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Information Disclosure statement (Paper No. 3) filed on 11/26/01 has been entered.
2. Applicant's election with traverse of Group I (claims 1-15 and 78-84) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the claims in Groups II, III and IV would not be a burden of search. This is not found persuasive because the claims in Group II-IV are drawn to different methods and are classified in separate class and subclass as compared to the product claims in Groups I. Applicants' argument regarding undue burden, is fully considered but found not persuasive because classification is prime basis for restriction which has not been rebutted simply because does not eliminate the burden in this case. Each case is examined on its own merits. The method steps are not necessary to practice the invention in Group I. Further (i) the issues are not the same with respect to 35 U.S.C.112 and 35 U.S.C. 101 statutes, (ii) separate Art Units would examine the Groups under ordinary circumstances. Thus the restriction requirement is still deemed proper.
3. Claims in Group I (claims 1-15 and 78-84) are considered for examination in this office action. Claims 16-77 are withdrawn from further consideration.
4. The specification is objected because of the following informalities:

Abstract of the specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Abstract of the instant specification is lengthy exceeding 150 words. Correction is required to reduce the words in the abstract.

Claim Rejections - 35 USC § 112

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims 1-2, 4-5, 7-8, 10 recite "about thirty or more labels" / about 40, 60...." / "about the same unit signal". It is unclear and indefinite because the term about is a relative term with respect to the claimed number of unique labels and it could include any number around the claimed number 30, 40, or 60 unique labels (i.e. it could include 20 or 22 or 29 or 33 or 39 with respect to "about thirty unique labels").

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (WO 99/52708).

Chandler teaches microparticles with multiple fluorescent signals wherein Chandler et al. disclose (i) a unique or distinct population of labels comprising one or more unique labels bound to DNA (microparticles) (see page 5, lines 28-34, page 6, lines 23-33, see page 8, lines 19-22); (ii) unique labels or dyes comprise unique emission spectra (see page 6, lines 2-4) which is unique to the specific set or population (see page 23, lines 17-25); (iii) unique labels comprise mixture of two or more (64 - 40,960) different or distinctly labeled particles created through variation of the amount of or type of dye (see page 17, lines 28-37, page 18, lines 1-15, page 6, lines 23-33); (iv) labels comprise fluorescent dyes (see page 15, lines 28-32). Thus the disclosure of Chandler meets the limitations in the instant claims.

B. Claims 1, 3-7, 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Glazer et al. (USPN. 6,428,667).

Glazer et al. teach multichromophore fluorescent probes comprising 20, or 100 or more bound to a nucleic acid molecule (see column3, lines 4-20, column 4, lines 3-11). Glazer et al. also teach that the labels comprise fluorescent labels (see column 3, lines 21-22, column 4, lines 12-17); labels comprise mixture of two different labels (see column 6, lines 60-68). Thus, the disclosure of Glazer et al. meets the limitations in the instant claims.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-15 and 78-84 rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (WO 99/52708) and in view of Chandler et al. (WO 99/37814).

Chandler teaches microparticles with multiple fluorescent signals wherein Chandler et al. disclose (i) a unique or distinct population of labels comprising one or more unique labels bound to DNA (microparticles) (see page 5, lines 28-34, page 6, lines 23-33, see page 8, lines 19-22); (ii) unique labels or dyes comprise unique emission spectra (see page 6, lines 2-4) which is unique to the specific set or population (see page 23, lines 17-25); (iii) unique labels comprise mixture of two or more (64 - 40,960) different or distinctly labeled particles created through variation of the amount of or type of dye (see page 17, lines 28-37, page 18, lines 1-15, page 6, lines 23-33); (iv) labels comprise fluorescent dyes (see page 15, lines 28-32). However Chandler did not teach labeled probes attached to unique labeled microparticle.

Chandler et al. ('814) teach microparticles attached with oligonucleotide probes wherein Chandler et al. disclose (v) uniquely labeled probes (fluorescent probes) comprising 20-50 fold concentration of target specific probes bound to the beads (see page 28, lines 20-33, page 29, lines 20-23);(vi) diverse population of uniquely labeled probes comprise two attached populations of nucleic acids, which include fluorescent probes and oligonucleotide bound to the bead (see page 29, lines 20-23); (vii) a kit comprising a series unique set of fluorescent labels

bound to a nucleic acid (genedigit) an a fluorescent probe (anti-genedigit), competitor molecule (specifier), a reference material (genedigit) (see page 6, lines 23-30).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made, to combine the labeled microparticles as taught by Chandler with the labeled probes as taught by '814 to achieve expected advantage of developing an efficient population of unique labeled probes because '814 suggests that "the fluorescent particles can be used for passive or covalent coupling of biological material such as haptens, enzymes or nucleic acids and used for various types of analyte assays applicable to medical, diagnostic and industrial applications." (see page 17, lines 31-33, page 18, lines 1-2). An ordinary practitioner would have been motivated to combine the teachings of Chandler with the teachings of Chandler et al. to achieve wide use of the uniquely labeled particles by incorporating the labeled probes because these limitations would improve the applicability of the unique labels in medical, diagnostic and industrial applications.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Art Unit: 1637

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
January 9, 2003



JEFFREY FREDMAN
PRIMARY EXAMINER